OCT 2 0 2005

KIRWAN® SURGICAL PRODUCTS

Page 1 of (2)

K052203

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

{as required by 21 CFR, section 807.92(c)}

FOR

MODELS 28-2000 & 28-2600, AURA, 70 WATT SERIES BIPOLAR ELECTROSURGICAL COAGULATORS

Common name: Electrical Surgical unit (ESU) / Electrosurgical Generator.

Classification name: Electrosurgical Cutting and Coagulation Device and Accessories (§878.4400)

Product code: GEI

The model 28-2000, Aura, 70 Watt Bipolar Electrosurgical Coagulator and the model 28-2600, Aura*plus*, 70 Watt Irrigating Bipolar Electrosurgical Coagulator are general purpose solid state bipolar generators used to supply the RF signal to electrosurgical hand-pieces used on soft body tissues where a wide range of tissue types, patient conditions, and load impedances are encountered. Where applicable (i.e., Aura*plus*) a peristaltic irrigation pump controls flow rate individually or simultaneously while coagulating.

Technological safety and effectiveness is established by the fact that the Aura 70, like its predicates, offers well-proven, basic electrosurgical unit technology. Its footswitch activation and solid state circuitry delivers low voltage RF/bipolar energy, interfacing with electrosurgical accessories via its standard 4mm female banana jacks. The Aura 70 differs technologically from its predicates with only minor operational features designed to enhance user interface. The following are some of those features.

- While operating on both 115 and 230 VAC mains supply as its predicates, the *Aura 70* does not require the placement of an external jumper in order to select between the two different voltage levels.

Kirwan Surgical Products, Inc.
180 Enterprise Drive
Marshfield, MA 02050
Phone: (781) 834-9500
Fax: (781) 834-0022
Contact: Kevin P. Prario,Regulatory Affairs Manager
Date prepared: 8/5/2005

- Activation of the Aura 70 is via footswitch only, eliminating the optional hand switch activation of its 28-1000 predicate, which is viewed as a little-used option and expendable in order to simplify construction, and limit size.
- While similarly relying on solid-state electronics, the *Aura 70* has been greatly simplified over some of its predicates by the use of microprocessor technology and modular medical-grade power supply.
- The Aura 70 uses membrane keypads instead of potentiometers (knobs) as adjustable controls for tonal volume and power level settings.

Performance safety has been tested in accordance with, and found to comply with, the requirements of the applicable sections of the following standards and guidelines;

- ANSI/AAMI/IEC 60601-1-2 (2001), Medical Electrical Equipment Part 1; General Requirements for the Safety.
- IEC 60601-2-2 (1998), Medical Electrical Equipment Part 2; particular Requirements for the safety of High Frequency Surgical Equipment.
- ANSI/AAMI HF 18 (2001), American National Standard for Electrosurgical Devices
- ANSI/AAMI/ISO 14971:2000, Medical devices – Application of risk management to medical devices.
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff (issued January 11, 2002).
- Guidance for FDA Reviewers and Industry. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (issued May 29, 1998).

Safety and hazard analysis has determined that the hazard conditions for the Aura 70 range in the low-to-moderate level and for this reason are acceptable.

Therefore, the Aura 70 is substantially equivalent in intended use, technological safety and effectiveness, and performance to the following predicates;

- *28-1000, Kirwan 50 Watt Bipolar Generator,*
- *26-2500, Aura, 20 Watt Bipolar Electrosurgical Coagulator,*
- *RF111, Pegasys Electrosurgical Generator, and*
- *80-1170, Malis™ Bipolar Electrosurgical System CMC-III.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2005

Kevin P. Prario
Regulatory Affairs Manager
Kirwan Surgical Products, Inc.
180 Enterprise Drive
Marshfield, Massachusetts 02050

Re: K052203
Trade/Device Name: Models 28-2000 and 28-2600, Aura 70 Watt Bipolar Electrosurgical Coagulators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 12, 2005
Received: August 16, 2005

Dear Mr. Prario:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Barbara Bruemmer for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052203

Device Name:

Models 28-2000 and 28-2600, Aura 70 Watt Bipolar Electrosurgical Coagulators

Indications for Use:

General purpose solid state bipolar generator to supply RF signal to electrosurgical hand-pieces used on soft body tissue where a wide range of tissue types, patient conditions and load impedances are encountered. Where applicable (i.e., Aura*plus*, 28-2600) a peristaltic irrigation pump controls flow rate individually or simultaneously while coagulating.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052203